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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,589	03/29/2004	Eric Tomasetti	TR-6132 (BXT 4021)	2100
7590	01/27/2006		EXAMINER	
Mr. Joseph B. Barrett Baxter Healthcare Corporation One Baxter Parkway, DF3-2W Deerfield, IL 60015			MC CLELLAND, KIMBERLY KEIL	
			ART UNIT	PAPER NUMBER
			1734	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Rm

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/811,589	TOMASETTI ET AL.
	Examiner	Art Unit
	Kimberly K. McClelland	1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 December 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8,16, and 17 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al.

With respect to claim 1, Yang et al. discloses a method for connecting flexible tubing wherein the tubing is placed in an axial end-to-end position (See Figures 2A and 2B), using a laser directed to heat the tube ends (paragraph 0068), and bringing them into contact with each other (paragraph 0071).

As to claim 2, Yang et al. is silent as to the temperature of the tubing ends before the laser is activated. However, in order for the tubing to be in a solid state prior to the welding process, the temperature of the tubing ends must be below the melting temperature of the material forming the tubing section. Yang et al. discloses that the laser melts the tubing (paragraph 0069).

As to claim 3, Yang et al. discloses the use of a material (film) to absorb energy from the laser at the tube ends (paragraph 0072).

As to claim 4, Yang et al. discloses a sheet of material (film), which has a high concentration of dye to absorb energy of the laser (paragraph 0072).

As to claim 5, Yang et al. discloses that the tubing material is substantially transparent (not laser responsive) to the electromagnetic beam (paragraph 0127).

As to claim 6, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071) and flow outward when heated (paragraph 0072).

As to claim 7, Yang et al discloses that dye may be applied to the tube ends (areas to be joined) that are welded by the laser (paragraph 0129).

As to claim 8, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071).

As to claim 16, Yang et al. discloses that the tubing sections are brought into contact (paragraph 0071), and flow outward (paragraph 0072).

As to claim 17, Yang et al. discloses that a laser is directed at the tube ends (paragraph 0068).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of U.S. Patent No. 5,674,333 to Spencer.

Yang et al. discloses a method for connecting two pieces of tubing as disclosed above. Yang et al. also discloses that all the welding method is carried out in the axial position (See Figures 4A-4F). However, Yang does not disclose cutting off end portions of the tubing sections.

As to claim 9, Spencer discloses an apparatus for welding together two sections of tubing, including a method of cutting of end sections of tubing prior to welding (column 3, lines 14-15). However, Spencer teaches this method while the tube sections are in a bent configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of cutting the tubing sections prior to welding, as taught by Spencer, with the laser welding method of Yang et al. in the axial position in order to ensure proper connection during welding.

5. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. and Spencer as applied to claim 9 above, and further in view of U.S. Patent No 4,832,773 to Shapaska et al.

Yang et al. and Spencer disclose a method of welding tubing sections together. Spencer also teaches the method of squeezing the tubing sections to reopen the

passage (column 3, lines 38-40). However, Yang et al. and Spencer do not disclose the clamping of the tubing.

As to claim 10, Shapaska et al. discloses a method for connecting sections of tubing, including clamping the cut (pre-cut) tubing sections (column 3, lines 48-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of clamping the tubing sections, as taught by Shapaska et al., with the laser welding method of Yang et al. and Spencer to keep the tubing sections stationary.

As to claim 11, Yang et al. discloses sealing the tube ends prior to welding the tubing sections together (paragraph 0072).

As to claim 12, Yang et al. discloses the use of a weld block (drum head) to absorb energy from the laser and combine with the tube (paragraph 0072).

As to claim 14, Spencer teaches the movement of welded tubing (weld sample) from one location (device) to a remote location (vise column 3, line 62- column 4, line 12)

As to claim 13, Spencer teaches the method of squeezing the tubing sections to reopen the passage (column 3, lines 38-40).

As to claim 15, Yang et al. discloses that all the welding method is carried out in the axial position (See Figures 4A-4F).

6. Claims 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0143352 A1 to Yang et al. in view of

U.S. Patent No. 6,860,960 B1 to Flanagan and U.S. Patent No. 4,793,880 to Shapaska et al.

Yang et al. discloses the method of laser welding an end cap film to a plastic tube, where the laser is directed at the energy absorption member (end cap), while the end cap is in contact with the tube (paragraph 0132). Yang et al. does not disclose melting or collapsing the tubing section during this process.

As to claim 18, Flanagan discloses a similar laser welding process, where the tubing material may be partially melted during the process (See Flanagan abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a method of allowing the tubing section to partially melt, with the laser welding method of Yang et al. to solidify and form a fusion bond (See Flanagan abstract).

Shapaska et al. discloses a sterile welding method, including collapsing at least a portion of the tubing section, prior to sealing, and sealing the collapsed tubing section portion in its collapsed configuration (See Figures 24, 25, 27, 46, and column 8, lines 44-47). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the collapsing step of Shapaska et al. with the welding method of Yang et al. The motivation would have been to exclude most of the fluid from the weld zone (Shapaska, column 1, lines 13-15). Therefore, it would have been obvious to combine Flanagan and Shapaska et al. with Yang et al. to obtain the invention as disclosed in claim 18.

As to claim 19, Yang et al. discloses the use of materials for end caps, which have low thermal conductivity (paragraph 0133). "Low" conductivity is a relative term, which carries little meaning without a reference point.

As to claim 20, Yang et al. discloses the use of a weld block (end cap) to absorb energy from the laser (See Figure 12 and paragraph 0132).

As to claim 22, Yang et al. discloses the use of a material (film) to absorb energy from the laser at the tube ends (paragraph 0072).

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Flanagan and U.S. Patent No. 4,793,880 to Shapaska et al. as applied to claims 18-20 and 22 above, and further in view of U.S. Patent No. 5,378,313 to Pace.

Yang et al., Flanagan, and Shapaska et al. disclose a laser welding method as taught above. Yang et al. also teaches that it is necessary to incorporate laser responsive components into materials to be bonded that are not laser responsive. However, Yang et al., Flanagan, and Shapaska et al. do not teach the use of glass or polytetrafluoroethylene laser responsive materials.

As to claim 21, Pace teaches that energy absorbing fillers, such as glass (column 5, line 20) may be used to form a laser responsive material (column 5, lines 21-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the glass taught by Pace with the end caps of the laser welding

method of Yang et al., Flanagan, and Shaposka et al. to absorb the energy of the electromagnetic beam (column 5, lines 23-24).

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. and Spencer as applied to claim 13 in the prior Office action, and further in view of U.S. Patent No 4,832,773 to Shaposka et al.

With respect to claim 23, Yang et al., Spencer, and Shaposka et al. disclose a method of welding tubing sections together as disclosed in the prior Office action. Further, Yang et al. discloses the step of providing material for absorbing energy comprises positioning a sheet of material between the axial surfaces of the tubing sections (See Yang et al. paragraph 0066), wherein the sheets are capable absorbing the energy of the electromagnetic beam (See Yang et al. paragraph 0072).

### ***Response to Arguments***

9. Regarding the rejection of claims 18-22 under 35 U.S.C. 103(a), in light of the amendment to the claims, the rejection is withdrawn.

10. Applicant's arguments filed December 1<sup>st</sup>, 2005 have been fully considered but they are not persuasive.

11. Regarding the rejection of claims 1-2 and 8 under 35 U.S.C. 102(e) applicant's argument that Yang et al. discloses exposing the tubing sections prior to forming a weld, examiner disagrees. Yang et al. discloses an alternate embodiment, wherein the laser

is reenergized after the tubing sections are placed in an opposed, end-to-end relationship (See Yang et al. Paragraph 0071).

12. Furthermore, the claim language, "exposure to the surrounding environment" must be broadly interpreted. In paragraph 12 of the specification, the applicant recites, "cutting tubing exposes interior passage to the environment." However, such language has multiple interpretations and must be read as such. Yang et al. discloses that prior to welding, the tubing sections may be sealed prior to the welding step, which would effectively prevent exposure to the surrounding environment (See Yang et al. paragraph 0066).

14. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., welding of the tubes occurs only after they are placed in end-to-end relationship) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. With respect to applicant's argument that in the Yang et al. reference, the tubing sections are already melting prior to being brought together, examiner disagrees. Yang et al. discloses that during preliminary laser activation, tubing sections may be melted or sterilized (See Yang et al. paragraphs 0069- 0071). It is known in the art that an electromagnetic beam sterilization process of plastic materials (such as tubing sections) does not require melting to occur (U.S. Patent No. 5,744,094 to Castberg et al., column 3, lines 33-42). Consequently, in the alternate embodiment wherein the laser is

reenergized after the tubing sections are placed in an end-to-end relationship, the tubing sections remain at sub-melting point temperatures prior to direct contact. Thus, claims 1-17 are unpatentable.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,744,094 to Castberg et al discloses the use of IR and UV radiation to sanitize plastic materials without melting the plastic (column 3, lines 6-10, and 33-42).

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly K. McClelland whose telephone number is (571) 272-2372. The examiner can normally be reached on 8:00 a.m.-5 p.m. Mon-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris A. Fiorilla can be reached on (571)272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
KKM

  
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Art 1734